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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,906	04/29/1999	DENNIS GONSALVES	07678/077002	6222

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Clark & Elbing, LLP
176 Federal Street
Boston, MA 02110

EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S-X-M.

Office Action Summary**Application No.**

09/301,906

Applicant(s)

GONSALVES ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,10,14,16-18,32-35 and 55-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-5,7,10,14,16-18 and 32-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6,35 and 55-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/24/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on November 24, 2003 has been entered.

Claims 8-9, 11-13, 15, 19-31 and 36-54 are cancelled.

Claim 6, 55, 58, 61 and 65 are currently amended.

Claims 1-7, 10, 14, 16-18, 32-35 and 55-67 are pending.

Claims 1-5, 7, 10, 14, 16-18 and 32-34 are withdrawn

Claims 6, 35 and 55-67 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

An Initialed and dated copy of Applicant's IDS form 1449 filed November 24, 2003 is attached to the instant Office action.

Claim Rejections - 35 USC § 112

Claims 6, 35 and 55-67 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the office action mailed May 20, 2003.

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Applicant's arguments filed November 24, 2003, have been fully considered but they are not persuasive.

Applicant argues that one skilled in the art would be able to make and use nucleic acid sequences encoding SEQ ID NO:5 without undue experimentation, as one need only confirm that the sequence encodes SEQ ID NO:5, a level of skill that is standard in the art. Applicant also argues that the cited reference of Doerks does not teach that homology is not useful in predicting function, and in fact teaches that homology should be carefully reviewed in order to predict the likely function of a protein. Applicant further argues that neither Doerks nor the Office provide any evidence or reason to doubt the existence of viral proteinase genes, and Applicant points to specific examples in the art, Maiti (Proc. Natl. Acad. Sci., 1993, Vol. 90, pages 6110-6114) and Vardi (Proc. Natl. Acad. Sci. Vol. 90, 1993, pages 7513-7517), of known plant viral proteinase genes in support of the assertion that there is little reason to doubt that one skilled in the art would question the proteinase function. (reply pages 11-12).

The Examiner does not dispute that the confirmation of the amino acid sequence encoded by a nucleic acid sequence is standard in the art, but maintains that the confirmation of an encoded amino acid sequence is not sufficient to enable the claimed invention, because the specification does not provide sufficient guidance for how to use such a sequence. Additionally, it has not been asserted by the Office that the existence of viral proteinase genes is doubted. The Maiti and Vardi references submitted by Applicant were in fact initially cited and discussed by the Examiner at page 6 of the office action mailed August 29, 2001. It also has not been asserted by the Office that homology is not useful in predicting function. It is asserted, however, that the homology between SEQ ID NO:5 and the Hepatitis C protease is not sufficient to establish a

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proteinase function for SEQ ID NO:5, or to establish the ability of SEQ ID NO:5 to confer viral resistance to a plant transformed therewith, because shared amino acid sequence homology suggests but does not confirm shared functional homology, and because the ability of even a functional sequence to confer viral resistance to a plant transformed therewith is unpredictable. Furthermore, neither the specification nor the record reveals a careful review of the homology between SEQ ID NO:5 and the Hepatitis C protease establishing that their shared structural homology is indicative of their shared functional homology.

Applicant additionally argues that the use of prophetic examples does not automatically make the specification nonenabling for conferring viral resistance to a plant by expressing sequences encoding SEQ ID NO:5, and Applicant points in particular to the disclosure at pages 13-16 of methods for generating and identifying plants having viral resistance. Applicant argues that the Office has not met the burden of establishing that the invention is not enabled as the techniques disclosed are standard in the art, and the employment of a single step screening approach for detecting viral resistance would not require undue trial and error experimentation on the part of the skilled artisan. (reply pages 12-13).

The Examiner acknowledges that the use of prophetic examples does not automatically make the specification nonenabling, but maintains that the disclosed prophetic examples do not enable the claimed invention because the ability of a particular viral transgene to confer viral disease resistance and to confer a particular spectrum of viral disease resistance to a plant transformed therewith is unpredictable, as set forth at page 6 of the office action mailed August 29, 2001. The Examiner further disagrees with the assertion that the screening approach for

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detecting viral resistance is a single step process that would not require undue trial and error experimentation on the part of the skilled artisan. The Examiner maintains that multiple steps would be required, both for plant transformation and plant screening. Multiple steps would be required, for example, to determine the appropriate part of the sequence to express, the appropriate promoter to use, which transformants to screen, which viral isolates to use as inocula, which amounts and concentrations of inocula to apply, and the appropriate time intervals for screening. It would require undue experimentation to carry out such steps because the specification provides no specific guidance for carrying them out using the claimed sequences.

Applicant also argues that the submitted references of Maiti (Proc. Natl. Acad. Sci., 1993, Vol. 90, pages 6100-6114) and Vardi (Proc. Natl. Acad. Sci. Vol. 90, 1993, pages 7513-7517) clearly support the notion that proteinase genes, such as the gene identified by applicant, can confer viral resistance when expressed in a plant (reply page 13).

With respect to the submitted references of Maiti (Proc. Natl. Acad. Sci., 1993, Vol. 90, pages 6100-6114) and Vardi (Proc. Natl. Acad. Sci. Vol. 90, 1993, pages 7513-7517), the Examiner maintains the position taken at page 6 of the office action mailed August 29, 2001, namely that while Maiti and Vardi teach that the expression of sequences encoding the potato virus Y (PVY) or tobacco vein mottling virus (TVMV) proteinases can confer resistance to PVY and TVMV respectively, the teachings of Maiti and Vardi as a whole support the assertion that the ability of a particular viral transgene to confer viral disease resistance and to confer a particular spectrum of viral disease resistance to a plant transformed therewith is unpredictable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

No claim is allowed.

Claims 6, 35 and 55-67 are deemed free of the prior art, due to the failure of the prior art to teach or suggest an isolated nucleic acid encoding the amino acid sequence of SEQ ID NO:5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CC
February 3, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in cursive script, appearing to read "David T. Fox", followed by a stylized "JY" or similar mark.